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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,816	10/02/2003	Dwight Jerome Holter		9791

7590 08/11/2005
Dwight Holter
1472 Murex Drive
Naples, FL 34102

EXAMINER

BOGART, MICHAEL G

ART UNIT PAPER NUMBER

3761

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	10/677,816	HOLTER, DWIGHT JEROME	
	Examiner	Art Unit	
	Michael G. Bogart	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>02 October 2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

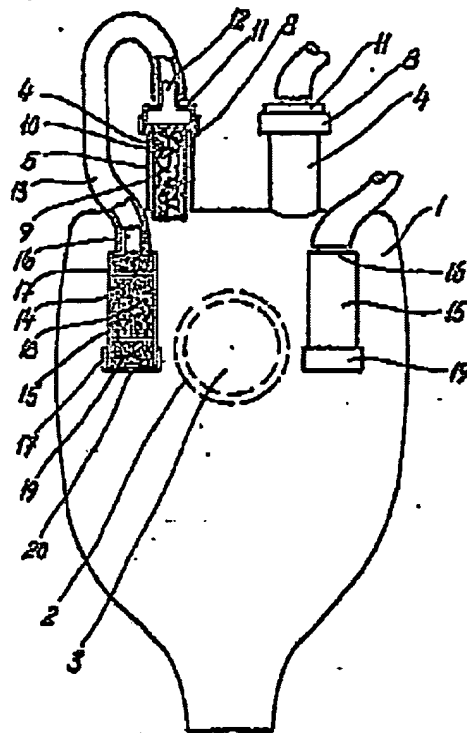
Claims 1, 3-14 and 20-23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kroack (DE 36 08 933 A1).

Regarding claim 1, Kroack teaches an ostomy bag comprising (a) a main chamber (1) with an upper extremity: (b) at least one multiple-use latent tube (4) co-formed with said main chamber (1), said multiple-use latent tube (4) having a proximal end firmly attached to, opening to and capable of fluid communication with said main chamber (1) upper extremity, said tube (4) further having a distal end (8) capable of providing axial gas flow out of said tube (4)(English abstract)(figure 1, below).

Regarding claim 3, Kroack teaches least one filter (5, 10) in fluid connection with said distal end (12) of said tube (4), for filtering the gaseous outflow from said ostomy bag.

Regarding claim 4, Kroack teaches a connector (11) is attached in fluid connection by axial insertion into said tube distal end (8) and said filter (5, 10) is connected to said connector (11).

Regarding claim 5, Kroack teaches that said filter (5, 10) is also a connector (5).



Regarding claims 6 and 7, Kroack teaches a plurality of multiple use latent tubes (4) co-formed with said main chamber (1)(figure 1).

Regarding claim 8, Kroack teaches that each of the tubes (4) is separately closable near its proximal end by cap member (11).

Regarding claims 9 and 10, The term "less than firm connection" in line 3 is a relative term which renders the claim unclear. The term "less than firm connection" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As such, this limitation is given minimal patentable weight.

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Further regarding claim 9, the main chamber (1) upper extremity has a perimeter edge, and said tube (4) has a perimeter edge which is in connection with a portion of the main (1) chamber upper extremity edge (figure 1).

Regarding claim 10, Kroack teaches a significant latent tube length between said proximal end and said distal end of the tube (4).

Regarding claim 11, Kroack teaches that the tube (4) is only connected to the main portion of the bag (1)(figure 1) at the proximal end of the tube (1).

Regarding claims 12 and 13, Kroack teaches that the distal end (8) of the tube (4) is capable of providing axial gas flow out of said tube (4).

Regarding claim 14, Kroack teaches an integral closing means (11) for closing the tube (4).

Regarding claim 20, Kroack teaches a process comprising routing gasses through a first tube (4) and a second tube (13) linked in series (figure 1).

Regarding claim 21, Kroack teaches that one of said tubes (4) is an integral part of an ostomy bag (1).

Regarding claim 22, Kroack teaches that one of the tubes (4) contains a filter material (10).

Regarding claim 23, Kroack teaches 23 that the second tube (13) is an elongated conduit for conducting flatus gas, said tube having two ends one proximal to and in fluid connection with said bag (1), the other end of said elongated tube being distal and connected to a firm tube (14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 16 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kroack.

Regarding claim 2, Kroack teaches that said main chamber (1) and said tube (4) have front-side and body-side walls, and the front-side wall of said main chamber (1) is made of the same kind of material as the front-side wall of said tube (4), and the body-side wall of said main chamber (1) is made of the same kind of material as the body side-wall of said tube (4). As can be seen from figure 1, the main bag portion (1) is integrally formed with the tubular extension members. Given that such devices are typically cast molded plastics, it is at least implied that the main body portion and tubular portions are made of substantially the same material.

"[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). MPEP § 2144.01.

Regarding claim 16, Kroack teaches a waste management system (1) for stomal wastes comprising multiple use latent tubing (13) having:

(a) front and back walls comprising thin, flexible, water impermeable plastic, said latent tubing (13) further having at least one channel having a flat width dimension and at least two end

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openings (12, 16), at least one of said end openings being a proximal end (12) through which gas can enter said tube (13), and the other a distal end (16) capable of providing axial fluid flow out of said tube (13), which latent tubing takes tubular form as necessary for venting of flatus gasses.

Kroack does not expressly teach the exact flat width dimension of the tubing channel. Mere changes in size alone are not sufficient to patentably distinguish a claimed invention over the prior art absent an unexpected result. *In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Regarding claim 19, Kroack teach tubing (13) connected to a tube (4) that is an integral part of an ostomy bag.

Allowable Subject Matter

Claims 15, 17 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

The art of record fails to teach either the slit of claim 15 or the pair of spaced apertures and interval seal of claims 17 and 18.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See Raiche (US 2,667,167) and Martell (US 6,007,525 A).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Bogart
06 August 2005

TATYANA ZALUKAEVA
SENIOR EXAMINER

